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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/521,524	03/08/2000	Beverly L. Davidson	875.025US1	1091

21186 7590 10/21/2003

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EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/521,524	DAVIDSON ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36 and 44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

In paper no. 31, applicant amended cancelled claims 37-43, amended claim 36 and added new claim 44. Claims 36 and 44 are under consideration.

Applicant's arguments and the declaration submitted under 37 CFR § 1.132 by Richard D. Anderson and Ronald E. Haskell have been fully considered and are found persuasive to overcome the new matter rejection of the last Office action. The examiner appreciates the thorough explanation applicant presented.

Double Patenting

Claim 44 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 36. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 44 is drawn to a method of producing recombinant adenovirus consisting of "contacting", while claim 36 is drawn to a method of producing recombinant adenovirus consisting of "transfecting". The materials used for contacting and transfecting are identical in both claims. Applicant states on page 3 of the response that support for claim 44 is found on page 8, lines 6-8. This passage of the specification discusses "co-transfection" with a backbone plasmid and a shuttle vector. Therefore, there does not appear to be a distinction between "contacting" in claim 44 and "transfecting" in claim 36.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 36 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoki et al. (Molecular Medicine. 1999; 5: 224-231) and He et al. (US 5,922,576) for reasons of record.

The claims are drawn to a method of producing a recombinant adenovirus consisting of transfecting a host cell with an adenovirus backbone plasmid comprising an adenovirus genome lacking map units 0 to 9.2 and a shuttle plasmid comprising adenovirus sequences from 0 to 1 map units and 9.2 to 16.1 map units of an adenovirus genome. The host cell is transfected with more molecules of the shuttle plasmid than molecules of the backbone plasmid.

Applicant states that the rejection is confusing because it cannot be determined whether Aoki et al. is the primary reference or not.

In response, the rejection is based upon the combination of teachings of Aoki et al. and He et al. Since it is impossible to discuss both teachings simultaneously, the references are presented one after the other.

Applicant argues that Aoki et al. teach a multi-step cloning system using equal moles of viral and plasmid DNAs in a cell-free reaction mixture. Applicant also argues that there is no suggestion in Aoki et al. to transfect host cells with more shuttle plasmid than backbone plasmid. Applicant states that the plasmids taught by He et al. are different from the instant plasmids and that there is no suggestion to substitute the ones used. Applicant also states that He et al.

disclose that a "key step" for producing adenovirus is co-transforming the linear DNA molecule and supercoiled bacteria into bacteria by conventional transformation methods. Applicant also argues that a reasonable expectation of success would not have been achieved unless the backbones of He et al. were used.

Applicant's arguments have been fully considered, but are found unpersuasive.

He et al. is not required to teach the specific plasmids recited in the claims because Aoki et al. do. If either of the references taught all of the elements in the claims, the rejection would have been made under 35 USC § 102. Contrary to applicant's assertions, the "key step" within the teachings of He et al. is stated in column 5, lines 5-15. The invention of He et al. concerns homologous recombination between two sequences having regions of homology. He et al. specifically state (column 5, lines 11-13), "In order to facilitate recombination between the linear DNA and the adenoviral vector, identical sequences must be present in both." In the instant case, the plasmids of Aoki et al. possess the identical sequences required for homologous recombination in the method of He et al. Therefore, a reasonable expectation of success is present to generate recombinant adenovirus in a one-step process for *in vivo* assembly in the method of He et al. with the plasmids of Aoki et al.

Finally, it is conceded that Aoki et al. teach using equal moles of viral and plasmid DNA. However, MPEP § 2144.05 states that "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA

1955)". In the instant case, there is no indication that the method demonstrates unexpected results since it is well established in the adenovirus art to generate recombinant adenovirus through homologous recombination with overlapping segments. In addition, there is no indication that the amount of shuttle and backbone plasmids are critical because the claims only require that there be "more" molecules of the shuttle plasmid than molecules of the backbone plasmid for the method to work.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley

JAMES HOUSEL 10/20/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600